DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

MJ481N

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No: DF2-0011512-2
Product: Heparin Controls in Blood Plasma

WARNING LETTER

FLA-99-32

February 3, 1999

Ms. Judy McInnis-Berger
Senior Regulatory Affairs
Dade Behring, Inc.
1717 Deerfield Road
Deerfield, Illinois 60015-3977

Dear Ms. McInnis-Berger:

The Food and Drug Administration (FDA) requested to examine a shipment of heparin controls in blood plasma offered for entry into the United States by your firm on or about August 5, 1998, under the above referenced entry number, and determined that the shipment was not available for FDA examination. Title 21, Code of Federal Regulations (CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen
Director, Florida District

Enclosure